Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

DATE: June 15, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Hi-Tech Pharmaceuticals, Inc.

SUGGESTED ACTION: **Unclassified Recall; Recall of All Lots of Stamina-Rx Dietary Supplement Products; Recommend notification to establishments that may carry these products via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. Stamina-Rx is sold predominantly in health food and drug stores nationwide. The product is sold in 10, 30, and 40-tablet bottles and in 2 and 6-tablet blister packs. Detail information is not available at this time. Please notify this office at 317-233-7360 if any recalled product is found.

****

Hi-Tech Pharmaceuticals, Inc. Issues Nationwide Recall of All Lots of Stamina-Rx Dietary Supplement Products

Contact:
Joseph P. Schilleci, Jr.
(205) 968-5300

FOR IMMEDIATE RELEASE – June 15, 2009 - Norcross, GA - Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), 6015-B Unity Dr., Norcross, GA 30071, announced today that it is conducting a nationwide voluntary recall of the company's product sold under the name Stamina-Rx.

On May 1, 2009, Hi-Tech was notified by the Food and Drug Administration (FDA) that FDA's lab analysis of one lot of Stamina-Rx samples found that the product contained the undeclared ingredient –

benzamidenafil – a Phosphodiesterase Type 5 (PDE5) inhibitor. The lot number found to contain benzamidenafil is Lot 08141578, Exp. 9/10. Benzamidenafil is in the same therapeutic class of active pharmaceutical ingredients that include the PDE5 inhibitors sildenafil, tadalafil, and vardenafil, that are FDA-approved for the treatment of erectile dysfunction (ED). Benzamidenafil is not FDA-approved, and poses a threat to consumers because benzamidenafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and may be most susceptible to adverse effects from this product.

Stamina-Rx is sold predominantly in health food and drug stores nationwide. The product is sold in 10, 30, and 40-tablet bottles and in 2 and 6-tablet blister packs.

In addition to the one lot described above, Hi-Tech is recalling all other lots of Stamina-Rx because it is an unapproved new drug and misbranded new drug in violation of the Federal Food, Drug and Cosmetic Act (the Act). FDA notified Hi-Tech that, based on certain labeling claims made by the firm, Stamina-Rx is a drug as defined in the Act. Stamina-Rx is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. The labeling at issue was not on bottles of Stamina-Rx, but was contained in certain web-based and print media.

Hi-Tech has been under a Consent Decree of Permanent Injunction with FDA since September 23, 2003. In accordance with the Decree, FDA determined that additional corrective actions were necessary for Hi-Tech to achieve compliance with the Act and the Decree and therefore, on May 1, 2009 FDA ordered Hi-Tech to recall all lots of Stamina-Rx to the consumer level.

Customers who have this product in their possession should stop using it immediately. Any adverse events that may be related to the use of this product should be reported to Hi-Tech Pharmaceuticals, Inc., Norcross, GA 30071 at toll-free 1-888-855-7919 from 9:00 AM - 5:00 PM EST.

The public is encouraged to submit a report of any serious adverse events that occur with the use of Stamina-Rx to FDA's MedWatch Adverse Event Reporting program online at [www.fda.gov/MedWatch/report.htm] or by phone [1-800-FDA-1088] or by returning the postage paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20853-9787 or fax [1-800-FDA-0178].

###